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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Applicant / Sponsor	
Name	Biomet UK, Ltd.
Address	Waterton Industrial Estate Bridgend, United Kingdom CF31 3XA
Establishment Registration Number	3002806535
Name of contact person	Jason Heckaman Regulatory Affairs Project Manager
Phone number	(574) 371-3707
Fax number	(574) 372-1683
Date prepared	December 20, 2013
Name of device	
Trade or proprietary name	Oxford® Fixed Lateral Bearing Partial Knee Replacement
Common or usual name	Unicondylar Knee Prosthesis
Classification name	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3530)
Classification panel	Orthopedic
Regulation	21 CFR §888.3530
Product Code(s)	HRY
Legally marketed device(s) to which equivalence is claimed	K122277 *Oxford* Fixed Lateral Bearing Partial Knee Replacement
Reason for 510(k) submission	Modification to tibial bearing design
Device description	The *Oxford* Fixed Lateral Bearing Partial Knee Replacement is a partial knee replacement option that consists of a femoral component (single and twin peg versions) manufactured from CoCrMo (ASTM F-75), a tibial tray/plate manufactured from CoCrMo (ASTM F-75), and a fixed tibial bearing of direct compression molded (DCM) polyethylene (UHMWPE) conforming to ASTM F-648 which is molded onto the tibial tray.

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	The subject of this submission is a design modification to add a chamfer to the anterior corner of the tibial bearing, resulting in asymmetric left and right configurations rather than the symmetrical design cleared in K122277.
Intended use of the device	Unicondylar Knee implant intended to replace part of a knee joint when used in conjunction with a femoral and tibial component.
Indications for use	Partial replacement of the articulating surfaces of the knee when only one side of the knee joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous partial arthroplasty in the affected compartment. The *Oxford* Fixed Lateral bearings are indicated for use in the lateral compartment and intended to be implanted with bone cement. The *Oxford* Femoral components are indicated for use in the lateral compartment for a fixed bearing application. They are intended to be implanted with bone cement.

Summary of the technological characteristics of the device compared to the predicate

The *Oxford* Fixed Lateral Bearing Partial Knee Replacement is a partial knee replacement option that consists of a legally marketed femoral component (single and twin peg versions) manufactured from CoCrMo (ASTM F-75), a tibial tray/plate manufactured from CoCrMo (ASTM F-75), and a fixed tibial bearing of direct compression molded (DCM) polyethylene (UHMWPE) conforming to ASTM F-648 which is molded onto the tibial tray. The biocompatible materials of the components are identical to the predicates and have a long history of orthopedic use. Both the subject and predicate tibial components are D-shaped for lateral use, incorporate the same tibial tray keel, and are offered in the same sizes. The subject tibial bearing differs slightly from the K122277 bearing in that the subject design has been modified to include an anterior chamfer to reduce the likelihood of femoral impingement. The subject and predicate devices are both indicated only for cemented use fixation.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Non-clinical performance testing included cadaver evaluation and MRI justification.

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Results indicate that the subject construct is substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
Clinical Performance Data/Information: None provided as a basis for substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject *Oxford* Fixed Lateral Bearing Partial Knee Replacement devices have been shown to be substantially equivalent to the predicate devices (K122277). Results of preclinical tests/engineering justification/cadaver evaluation and the similarities with legal marketed predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

Biomet, Incorporated
Jason Heckaman
Regulatory Affairs Project Manager
56 East Bell Drive
Warsaw, Indiana 46581

Re: K133940
Trade/Device Name: Oxford® Fixed Lateral Bearing Partial Knee Replacement
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: March 7, 2014
Received: March 10, 2014

Dear Mr. Heckaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133940

Device Name: Oxford Fixed Lateral Bearing Partial Knee Replacement

Indications For Use:

Partial replacement of the articulating surfaces of the knee when only one side of the knee joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous partial arthroplasty in the affected compartment.

The Oxford Fixed Lateral bearings are indicated for use in the lateral compartment and intended to be implanted with bone cement.

The Oxford Femoral components are indicated for use in the lateral compartment for a fixed bearing application. They are intended to be implanted with bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices